PREMARKET NOTIFICATION

MAY 2 9 2013

510(k) SUMMARY

(As Required By 21 CFR 807.92)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____ Date: APR 17 2013

1. Submitter:

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2. Name of the Device:

Trade Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL858CA
Common Name: Blood Pressure Monitor
Classification Name: Non-invasive Blood Pressure Measurement System
Classification: Class II
Regulation Number: 21 CFR 870.1130
Product Code: DXN
Panel: 74 Cardiovascular

3. Information for the 510(k) Cleared Device (Predicate Device):

Full Automatic (NIBP) Blood Pressure Monitor, Model HL868RT, K093831

4. Device Description:

HL858CA automatically measures human's Systolic, Diastolic blood pressure and heart

rate by using the oscillometric method. All values can be read out in one LCD panel. Measurement position is at human being's upper arm. The intended use of this over-the-counter device is for adults aged 18 years and older with arm circumference ranging from 9 inches to 17 inches (approx.23 cm to 43 cm) and for home use.

The device will display a symbol or , to indicate the detection of irregular heartbeat rhythm as defined as a rhythm is more than or less than 25% from the average heartbeat intervals during the measurement. Additionally, after measurement, the Risk Category Indicator function will show the information with the readings on the screen for the user tracking their blood pressure level. Furthermore, the user can save and manage the measurement data by transferring the measured readings of blood pressure to the connected personal computer (PC) via USB cable.

Besides, When Triple Check mode is turned on by user, the symbol ( ) will display on the LCD. Then press Start/Stop button the device will take three consecutive measurements automatically at 1 minute intervals. After measurements are completed, LCD will display the average values of the three measurements. And this device is designed with Rest Assure function as a countdown timer to help user in relax state for 5 minutes before taking measurement.

5. Intended Use

This device automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. All values can be read out in one LCD panel. Measurement position is at human being's upper arm. The intended use of this over-the-counter device is for adults aged 18 years and older with arm circumference ranging from 9 inches to 17 inches (approx.23 cm to 43 cm) and for home use.
When the device detects the appearance of irregular heartbeats during measurement, an indicated symbol will appear with measuring readings. And this device can let the memory data be transferred to the connected personal computer (PC) via USB cable.

6. Comparison of device to predicate device:

Product Specification Comparison Table of HL858CA and HL868RT (K093831)

Item	Predicate Device HL868RT (K093831)	Subject Device HL858CA
Method of measurement	Oscillimetric	Same as left

Range of measurement	Pressure 0- 300mmHg, Pulse 40-199 Beats/minute	Same as left
Accuracy	Pressure +/− 3mmHg Pulse +/− 5%	Same as left
Inflation	Automatic inflation (Air pump)	Same as left
Deflation	Automatic air release control valve	Same as left
Exhaust	Automatic exhaust valve	Same as left
Display	Liquid Crystal Digital Display	Same as left
Power Supply	AA (1.5V) Alkaline batteries× 4 or 6V 1A AC adapter	Same as left
Storage/ Transportation Environment	- 20℃ ~ + 70℃ (- 4°F~ +158°F), ≦ 90% R.H.	- 25℃ ~ + 70℃ (- 13°F~ +158°F), ≦ 93% R.H.
Operating Environment	10℃ ~ 40℃ (50°F~104°F), 15% ~ 90%R.H.	5℃ ~ 40℃ (41°F~104°F), 15% ~ 93% R.H.
Material	ABS housing and rubber keys	ABS housing and ABS keys
Sets of memory	2*60, total 120	2*120, total 240
Number of Push Button	7	7 + 2 switch control (Triple check, Rest assure)
Storage pouch	Yes	Same as left
Cuff size	Arm circumference approx. 23-43 cm (9~17 inches)	Same as left
Unit Weight	Approx. 293 ± 5g (Excluding Batteries)	Approx. 393 ± 10g (Excluding cuff and Batteries)

Changes from the predicate devices HL868RT (K093831):

*Changing of exterior casing design and the material of keys

* Additional product features of Triple check function, and Rest Assure Function.

These additional feature has been verified and validated and do not affect the safety and effectiveness of subject device HL858CA.

7. Discussion of Clinical Tests Performed:

HL858CA is compliant to the ANSI/AAMI SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002 /A1:2003/(R) 2008 & ANSI/AAMI SP10:2002/ A2:2006/(R) 2008 Manual, electronic or automated sphygmomanometers. All the relevant activities were performed by designate individual(s) and the results demonstrated that the predetermined acceptance criteria were fully met.

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The subject device was tested to evaluate its safety and effectiveness, including the followings:

a. **Safety Test:**
   -IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
   -IEC 60601-1-11:2010, Medical electrical equipment-Part 1-11: General Requirement for basic safety and essential performance – Collateral Standard: Requirements for medical electrical systems used in the home healthcare environment.

b. **EMC Test**: IEC 60601-1-2 Edition 3:2007-03 Medical Electrical Equipment - Part 1-2: General requirements for safety - collateral standard: Electromagnetic compatibility - Requirements and Tests.

c. **Reliability Test**: ANSI/AAMI SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002 /A1:2003/(R) 2008 & ANSI/AAMI SP10:2002/ A2:2006/(R) 2008 Manual, electronic or automated sphygmomanometers.

d. **Risk Assessment**: ISO 14971:2007 Second Edition, Medical devices - Application of risk management to medical devices

e. **Software Verification and Validation**: IEC 62304 Ed.1.0(2006), Medical device software - Software life cycle processes, and IEC 60601-1-4 Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems, edition 1.1

f. **Usability Validation**: IEC 62366:2007 Medical devices - Application of usability engineering to medical devices

9. Conclusions:

The subject device was tested and fulfilled the requirements of those standards mentioned

above, and it's concluded that the subject device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 29, 2013

Health & Life Co., Ltd.
c/o Ms. Sarah Su, Manager
Regulatory Affairs Dept.
9F, No. 186, Jian Yi Road
Zhonghe District, New Taipei City
Taiwan 23553

Re: K131121
Trade/Device Names: Full Automatic (NIBP) Blood Pressure Monitor, Model HL858CA
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: April 25, 2013
Received: April 29, 2013

Dear Ms. Su:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ___K131121_____

Device Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL858CA

Indications for Use:

This device automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. All values can be read out in one LCD panel. Measurement position is at human being's upper arm. The intended use of this over-the-counter device is for adults aged 18 years and older with arm circumference ranging from 9 inches to 17 inches (approx.23 cm to 43 cm) and for home use.

When the device detects the appearance of irregular heartbeats during measurement, an indicated symbol will appear with measuring readings. And this device can let the memory data be transferred to the connected personal computer (PC) via USB cable.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __V___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Devices Evaluation (ODE)

Owen P. Faris -S
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